

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2004/003789

International filing date (day/month/year)
19.11.2004

Priority date (day/month/year)
17.03.2004

International Patent Classification (IPC) or both national classification and IPC
C07D207/34

Applicant
RANBAXY LABORATORIES LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/003789

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/003789

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-31,33-47
	No: Claims	32
Inventive step (IS)	Yes: Claims	1-31,33-47
	No: Claims	32
Industrial applicability (IA)	Yes: Claims	11-47
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V.

- 1 The following documents are referred to in this communication:

D1 : WO 03/068739 A (LECIVA, A.S; RADL, STANISLAV; STACH, JAN) 21 August 2003 (2003-08-21)
D2 : WO 02/083637 A (CADILA HEALTHCARE LIMITED; AGARWAL, VIRENDRA, KUMAR; VAKIL, MANISH, HA) 24 October 2002 (2002-10-24)
D3 : WO 02/083638 A (CADILA HEALTHCARE LIMITED; AGARWAL, VIRENDRA, KUMAR; VAKIL, MANISH, HA) 24 October 2002 (2002-10-24)
D4: WO 97/03960 A (WARNER-LAMBERT COMPANY; LIN, MIN; SCHWEISS, DIETER) 6 February 1997 (1997-02-06)
D5: US-B1-6 646 133 (GREFF ZOLTAN ET AL) 11 November 2003 (2003-11-11)
D6: WO 01/42209 A (LEK PHARMACEUTICAL AND CHEMICAL COMPANY D.D; PFLAUM, ZLATKO) 14 June 2001 (2001-06-14)

2. **Novelty**

The process for the production of atorvastatin calcium appears to differ from the processes disclosed in D1 to D3 in the purifying step f) in which a mixture of tetrahydrofuran and methanol is used for dissolving the crude atorvastatin calcium. The step is also claimed per se in claim 2. D4 discloses the same step by using tetrahydrofuran while in D5 the same step is carried out by using an alcohol. The process disclosed in claim 32 is considered to be anticipated by D6.

It is noted that the independent claims do not all share the same differentiating features with respect to the prior art; a non-unity objection could be raised during the examination of the present case.

3. **Inventive step**

As regards the overall process as claimed in claim 1, since the combination of a non-polar and a polar solvent for the preparation of atorvastatin calcium in crystalline form from crude atorvastatin calcium is not considered to be suggested in the cited prior art, inventive step is acknowledged.

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International application No.

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4. Claim 47 contains a reference to the description and does not contain any technical features.